

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: PETER PAL VARGA, et )  
al. )  
TITLE: INTERVERTEBRAL SPACING )  
IMPLANT SYSTEM )  
SERIAL NO.: ) PRELIMINARY AMENDMENT  
FILED: )  
EXAMINER: )  
ART UNIT: )  
)  
)  
)  
)

---

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Preliminary to the examination of the above-captioned application, please enter this Amendment and reconsider the above captioned application in view of the amendments and the remarks provided below.

---

CERTIFICATE OF EXPRESS MAILING

DATE OF MAILING January 22, 2002 EXPRESS MAIL LABEL NO: ET243162730US  
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service on the date indicated above and is addressed to: Commissioner for Patents, Washington D.C. 20231

  
Karl R. Cannon  
Attorney Registration No. 36,468  
Attorney for Applicant

Please amend the above-captioned application as follows:

Version of Amendments with Markings to Show Changes Made.

IN THE SPECIFICATION:

On page 1, please amend the title as indicated below:

INTERVERTEBRAL [SPACER] SPACING IMPLANT SYSTEM

On page 14, starting at line 1, please replace the first paragraph with the following:

The unique aspects and procedures relating to the spacer 10 will now be explained in more detail. Some of the key features of the invention comprise the size, shape and placement of spacer 10. The spacer 10 is preferably made of titanium, thus having a non-porous quality with a preferably smooth finish. The spacer 10 could also be made of ceramic, or any other suitable material that is inert or [and] biologically compatible. The term "non-porous" as used herein shall be construed broadly in accordance with the common, ordinary meaning of that term to refer to objects possessing an impediment to flow that would operate in the presence of fluid to impede or even block fluid flow through the object. In accordance with such common, ordinary meaning, such objects are either impermeable by liquid, or possess a limited degree of permeability that prevents liquid from passing

through the object in a manner that would be considered flow.  
Examples of objects that are non-porous and impermeable include a  
solid titanium or solid ceramic intervertebral spacer, or a  
spacer made from impermeable bone material, or a spacer that is  
coated or treated in some way to render it impermeable. Examples  
of objects that are non-porous and possess a limited degree of  
permeability, and which therefore do not permit fluid to pass  
through them in a flowable manner, include biologically  
compatible spacers made from bone, such as milled-bone allograft  
spacers or particle-bone allograft spacers that are freeze-dried  
and thereafter re-hydrated prior to insertion, or any other type  
of non-porous spacer made from bone. Under the definition above,  
the presence or absence of surface porosity on an object, such as  
an intervertebral spacer, is irrelevant to whether the object is  
porous or non-porous. The spacer 10 is thus constructed from a  
rigid, non-resilient load-bearing material, one that is  
preferably incapable of elastic deformation. The spacer 10, by  
its anterior, convex sidewall 12 and its posterior, concave  
sidewall 14, has thereby a concavo-convex contour with respect to  
one dimension.

Clean Version of Amendments.

IN THE SPECIFICATION:

On page 1, please replace the title with:

INTERVERTEBRAL SPACING IMPLANT SYSTEM

On page 2, after CROSS-REFERENCE TO RELATED APPLICATIONS,  
please insert the following paragraph:

This application is a division of co-pending U.S. Patent Application Serial No. 09/592,072, filed June 12, 2000, entitled "INTERVERTEBRAL SPACER" which is hereby incorporated by reference herein in its entirety, including but not limited to those portions that specifically appear hereinafter.

On page 14, starting at line 1, please replace the first paragraph with the following:

The unique aspects and procedures relating to the spacer 10 will now be explained in more detail. Some of the key features of the invention comprise the size, shape and placement of spacer 10. The spacer 10 is preferably made of titanium, thus having a non-porous quality with a preferably smooth finish. The spacer 10 could also be made of ceramic, or any other suitable material

that is inert or biologically compatible. The term "non-porous" as used herein shall be construed broadly in accordance with the common, ordinary meaning of that term to refer to objects possessing an impediment to flow that would operate in the presence of fluid to impede or even block fluid flow through the object. In accordance with such common, ordinary meaning, such objects are either impermeable by liquid, or possess a limited degree of permeability that prevents liquid from passing through the object in a manner that would be considered flow. Examples of objects that are non-porous and impermeable include a solid titanium or solid ceramic intervertebral spacer, or a spacer made from impermeable bone material, or a spacer that is coated or treated in some way to render it impermeable. Examples of objects that are non-porous and possess a limited degree of permeability, and which therefore do not permit fluid to pass through them in a flowable manner, include biologically compatible spacers made from bone, such as milled-bone allograft spacers or particle-bone allograft spacers that are freeze-dried and thereafter re-hydrated prior to insertion, or any other type of non-porous spacer made from bone. Under the definition above, the presence or absence of surface porosity on an object, such as an intervertebral spacer, is irrelevant to whether the object is porous or non-porous. The spacer 10 is thus constructed from a rigid, non-resilient load-bearing material, one that is

preferably incapable of elastic deformation. The spacer 10, by its anterior, convex sidewall 12 and its posterior, concave sidewall 14, has thereby a concavo-convex contour with respect to one dimension.

**IN THE CLAIMS:**

Please cancel claims 1-25 and 32-43, without prejudice.

Please add new claims 44-62 as indicated below:

44. (New) An intervertebral spacing implant system comprising:

a spacing member adapted for implanting between adjacent intervertebral bodies of a human spine, said spacing member comprising an external, non-porous, concavo-convex contour with respect to one dimension of said spacing member; and

positioning means for enabling a surgeon to adjust a position of the spacing member when said spacing member resides between adjacent intervertebral bodies, said positioning means comprising an elongate member, and a means for releasably attaching the elongate member to the spacing member.

45. (New) The intervertebral spacing implant system of claim 44 wherein said spacing member further comprises a first

end and a second end, wherein said first end comprises complementary means for releasably attaching the elongate member to the spacing member.

46. (New) The intervertebral spacing implant system of claim 45 wherein said complementary means for releasably attaching the elongate member to the spacing member comprises a recess in said spacing member.

47. (New) The intervertebral spacing implant system of claim 46 wherein said complementary means for releasably attaching the elongate member to the spacing member comprises threads in said recess.

48. (New) The intervertebral spacing implant system of claim 44, wherein said elongate member comprises a sheath member and a rod member slidably insertable into the sheath member.

49. (New) The intervertebral spacing implant system of claim 48, wherein the rod member has a longer length than the sheath member, such that a proximal portion of the rod member protrudes from the sheath member when said rod member resides within said sheath member and is attached to the spacing member.

50. (New) The intervertebral spacing implant system of claim 44, wherein the means for releasably attaching the elongate member to the spacing member further comprises a threaded engagement.

51. The intervertebral spacing implant system of claim 50, wherein the means for releasably attaching the elongate member to the spacing member further comprises a female threaded recess formed in the spacing member, and wherein the elongate member comprises a male threaded distal end having a size and configuration sufficient to permit threaded engagement between said male threaded distal end of the elongate member and the female threaded recess formed in the spacing member.

52. (New) The intervertebral spacing implant system of claim 45 wherein said second end of said spacing member comprises a taper in a medial-lateral direction.

53. (New) The intervertebral spacing implant system of claim 44 wherein said spacing member comprises a planar upper surface and a planar lower surface, said spacing member further comprising a solid configuration characterized by the absence of through holes between said planar upper surface and said planar lower surface.

54. (New) An intervertebral spacing implant system comprising:

a spacing member adapted for implanting between adjacent intervertebral bodies of a human spine, said spacing member comprising an external, concavo-convex contour with respect to one dimension of said spacing member, said spacing member further comprising a first end and a second end, wherein said first end comprises attachment means for releasably attaching positioning means to said spacing member, and said second end comprises a taper such that a thickness of said second end is less than a thickness of said first end; and

positioning means for enabling a surgeon to adjust a position of the spacing member when said spacing member resides between adjacent intervertebral bodies.

55. (New) The intervertebral spacing implant system of claim 54 wherein said spacing member is non-porous.

56. (New) The intervertebral spacing implant system of claim 54 wherein said attachment means for releasably attaching positioning means to said spacing member comprises a recess in said spacing member.

57. (New) The intervertebral spacing implant system of claim 56 wherein said attachment means for releasably attaching positioning means to said spacing member further comprises threads in said recess.

58. (New) The intervertebral spacing implant system of claim 54, wherein said positioning means comprises a sheath member and a rod member slidably insertable into the sheath member.

59. (New) The intervertebral spacing implant system of claim 58, wherein the rod member has a longer length than the sheath member, such that a proximal portion of the rod member protrudes from the sheath member when said rod member resides within said sheath member and is attached to the spacing member.

60. (New) The intervertebral spacing implant system of claim 54, wherein the attachment means for releasably attaching positioning means to said spacing member further comprises a threaded engagement.

61. The intervertebral spacing implant system of claim 54, wherein the attachment means for releasably attaching positioning means to said spacing member further comprises a female threaded

recess formed in the spacing member, and wherein the positioning means comprises a male threaded distal end having a size and configuration sufficient to permit threaded engagement between said male threaded distal end of the elongate member and the female threaded recess formed in the spacing member.

62. (New) The intervertebral spacing implant system of claim 54 wherein said spacing member comprises a planar upper surface and a planar lower surface, said spacing member further comprising a solid configuration characterized by the absence of through holes between said planar upper surface and said planar lower surface.

#### REMARKS

Applicant requests that this Amendment be entered prior to examination of this application. The subject matter added to the claims is supported in the disclosure, inter alia, in FIGS. 6 and 7, and is therefore not new matter. Amendments to the specification have been made as supported in the disclosure, inter alia, (i) by the original specification's reference to the term "non-porous," and (ii) by the original reference in the specification to "biologically compatible" and (iii) by the original reference in the specification to "inert," and (iv) by the original reference in the specification to multiple types of

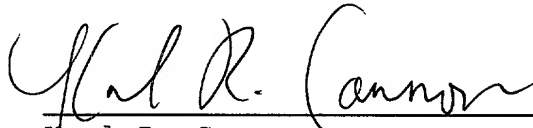
materials that meet those already-mentioned criteria. The original specification already supported the idea that materials that are inert or biologically compatible, such as titanium, or ceramic, or any other suitably compatible material, can be used to construct the invention. Also, the word "and" and "or" can both be either conjunctive or disjunctive, and so the amendments to the specification amounts to mere clarification, i.e. the original specification referred to materials that are either inert or biologically compatible. Accordingly, the rephrasing of the passage does not constitute new matter.

In view of the foregoing, applicants believe that claims 26-31, and 44-62 are all allowable and the same is respectfully requested. If any impediment to the allowance of these claims remains after entry of this Amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to initiate the same.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 50-0836.

DATED this 22 day of January, 2002.

Respectfully submitted,



Karl R. Cannon  
Attorney Registration No. 36,468  
Attorney for Applicant

Clayton, Howarth & Cannon, P.C.  
P.O. Box 1909  
Sandy, UT 84091  
Telephone: (801) 255-5335  
Facsimile: (801) 255-5338

KRC/CBV

S:\CHC Files\T 9--\T93--\T9376\DIV1\prelim.amend.wpd